CARILION CLINIC IRB Review

Monthly updates from the Human Research Protections Office (HRPO) Issue 24/ August 2025

Thank You to Our Research Partners

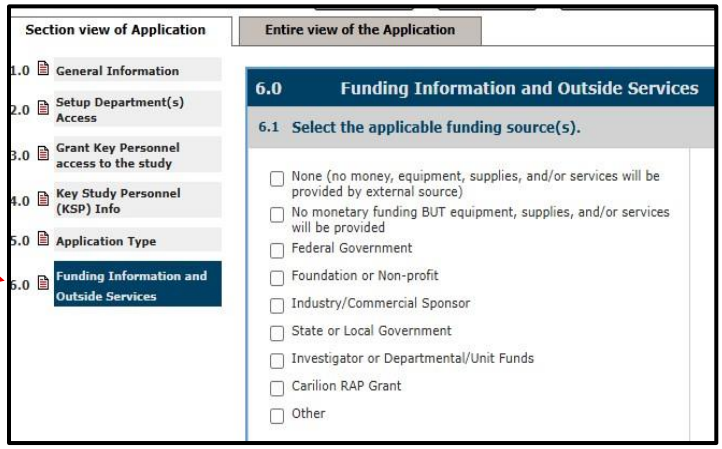
We wanted to extend our gratitude to all the department leaders for taking the time to meet with Meredith Talmadge, Director of HRPO, and Dr. Charles Schleupner, IRB Chair. The feedback we received has been invaluable in helping develop an advocacy plan aimed to promote excellence in the conduct of ethical and compliant research. The advocacy plan is built on a foundation of shared commitment and responsibility, and by working together, we can streamline the IRB submission process. Your commitment to advancing ethical and compliant research has been instrumental in the remarkable 30% increase in new Carilion Clinic research studies over the past three years (2022-2024). Researchers interested in learning more about the advocacy plan or to offer feedback, please contact irb@carilionclinic.org .

HRPO Advocacy Plan to Enhance Research Support

Department-Focused Recommendations	PRIS3M System Enhancements
• Establish primary regulatory support persons in each department • Implement departmental scientific review before IRB submission • Schedule focused IRB training tailored to departmental needs • Ensure adequate time allocation for study development	• Live support for navigation and submission tracking • Screen-sharing demonstrations for individual projects • Updated user guides and regulatory guidance • Automated reminder emails at 15, 30, 45, and 60-day intervals • IRB Application Templates on website
Researcher-Centered Services	**Communication Improvements**
• Proactive outreach when R&D/DoM approvals are received • Clearer, action-oriented stipulation wording • Quick-tip documents for common research categories • Increased staff availability for protocol development support	• Opportunity to copy department leaders on stipulations • Quarterly meetings with research leaders • One-business day response time commitment • Direct scheduling links in analyst email signatures

Funding Information & Outside Services

Reminder: Both monetary and non-monetary sources of support need to be disclosed in IRB Application Section 6: Funding Information and Outside Services. This includes internal funding, federal funding/grants, subawards, donated supplies, equipment, laboratories, drugs, devices, or other forms of support. These specific details are essential for the review process and for the Compliance department that manages Conflict of Interest (COI).



Standard Operating Guideline (SOG) 4.1 Updated on IRB Website

Click on the icon below to view
SOG 4.1: Investigational Drugs and Biologics

Federal Agency Communications

Deadline for Executive Order "Restoring Gold Standard Science"

All federal agencies must report their implementation actions to Office of Science and Technology (OSTP) by August 22, 2025 as a result of this executive order. On June 23, 2025, OSTP Policy Director Michael Kratsios issued guidance to federal agencies on incorporating Gold Standard Science tenets into research activities that can be found here.

Resources Center

September PRISM Class

Researchers can learn the basics of navigating PRIS3M and beginning a study submission application. The first 30 minutes will be led by Hilary to take you through an overview of PRISM. The remaining 30 minutes will be dedicated to questions and addressing specific needs from attendees. You must register to attend.

Register here for **Monday, September 22, 2025** from **12-1 PM**. You will need to use your Carilion Active Directory credentials to register for class.

HRPO Personalized Services

Contact our office at irb@carilionclinic.org for the following:

- New to IRB study submission
- Consultations for studies
- Specific study questions
- Schedule IRB training
- Guided help for PRISM
- Assistance with IRB regulatory requirements
- General questions

We tailor our support to each researcher's schedule and expertise level, ensuring they receive exactly the assistance they need.